

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/530,013 04/24/00 SHIMIZU

H 32-254P

002292 HM12/0820
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EXAMINER

GTTOMEE P

ART UNIT

PAPER NUMBER

1623

DATE MAILED:

08/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/530,013	Applicant(s) Shimizu et al.
Examiner Ralph Gitomer	Art Unit 1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Apr 24, 2000

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-8 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-8 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 20) Other: _____

The IDS received 7/11/00 has been entered and claims 1-9 are currently pending in this application. It is noted no references have been received with the IDS of 4/24/00.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

10 A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15 Claims 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Applicants' admissions in the specification.

Claims 7-8 read on a container made of or coated with silicone or plastic and does not contain aprotinin. Such containers are widely commercially available for many years.

20 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

25 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Lindberg in view of Clerico.

Lindberg (Pharmacology & Tox) entitled "Adsorption of Atrial Natriuretic Peptide to Different Materials" teaches on page 278 column 2 first paragraph, loss of recovery of ANP at different concentrations in different containers was determined where the containers include siliconized glass and coated polymers.

The claims differ from Lindberg in that they are directed to a method for inhibiting degradation of the peptides and Lindberg is directed not to storage but to contacting containers only as related to concentration.

Clerico (Clin Chem) entitled "Analytical Performance and Clinical Usefulness of a Commercially Available IRMA Kit for Measuring Atrial Natriuretic Peptide in Patients With Heart Failure" teaches on page 1631 column 2 last paragraph, storage of ANP degrades it.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the containers of Lindberg which show the greatest recovery of ANP to store ANP containing specimens as shown by Clerico because Clerico teaches storing ANP in general degrades it. It would appear from Lindberg 5 the silicone coated containers do not degrade ANP as much as others and would therefor desirable for storage of ANP which is known to be sensitive to degredation in storage.

Claims 5 and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing 10 subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 5 and 8 are directed to the specimen does not contain aprotinin. This is not found in the specification.

15
Claims 2-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain specific silicones and polymers, does not reasonably provide enablement for "silicone or plastic". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly 20 connected, to make and use the invention commensurate in scope with these claims.

In claim 2 the terms "silicone or plastic" lack enablement as it would require one of ordinary skill in this art undue experimentation to determine which such substance would work in the instant invention.

The entire scope of the claims has not been enabled because:

- 5 1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative compounds claimed.
2. Amount of direction or guidance presented is insufficient to predict which substances encompassed by the claims would work.
3. Presence of working examples are only for specific substances and extension to other compounds has not been specifically taught or suggested.
4. The nature of the invention is complex and unpredictable.
5. State of the prior art indicates that most related substances are not effective for the claimed functions.
6. Level of predictability of the art is very unpredictable.
7. Breadth of the claims encompasses an innumerable number of compounds.
8. The level of one of ordinary skill in this art is variable.

In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

Claims 1-8 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

The claims must be rewritten in clear and proper idiomatic English according to standard US patent practice. Claim 1 as presented is entirely functional where something is inhibited by inhibiting it. In the first instance in the claims "BNP" should be spelled out. Claim 6 is directed to a method for measuring but contains no such method steps to perform the method of the preamble.

5 The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

10 The Abstract of the Disclosure is objected to because it is not in proper English and is two paragraphs. Correction is required. See M.P.E.P. § 608.01(b).

15 The disclosure is objected to because of the following informalities: The specification should be carefully reviewed for English and typographical errors. The distinction between silicon and silicone may be important. Appropriate correction is required.

20 The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

deBold (4,663,437 and 4,647,455) teach ANP.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist can be reached on (703) 308-1701. The fax phone number for this Art Unit is (703) 308-4556.

5 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1234. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button "Patent 10 Electronic Business Center" for more information.

R. Gitomer

15 Ralph Gitomer
Primary Examiner
Group 1623

RALPH GITOMER
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